

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL BAR-SHALOM

Appeal No. 2003-0816
Application No. 09/693,254

HEARD: August 21, 2003

Before KIMLIN, JEFFREY T. SMITH and POTEATE, *Administrative Patent Judges*.

JEFFREY T. SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

Applicant appeals the decision of the Primary Examiner finally rejecting claims 1, 2, 4 to 7, 9 to 14, 16 to 27 and 35 to 54.^{1,2} We have jurisdiction under 35 U.S.C. § 134.³

¹ The claims on appeal have been amended in the after final response filed January 12, 1999, which has been entered by the Examiner. (Answer, p. 2).

² According to Appellant, Brief page 3, the Examiner has indicated that claims 3, 8 and 34 contain allowable subject matter.

³ In rendering our decision we have considered Appellant's position as presented in the Brief, filed June 24, 1999 and the Reply Brief, filed December 6, 1999.

CITED PRIOR ART

As evidence of unpatentability, the Examiner relies on the following references:

Banker	4,330,338	May 18, 1982
Conte et al. (Conte)	5,422,123	Jun. 06, 1995
Bar-Shalom et al. (WO' 066) (Published PCT International patent application)	WO 89/09066	Oct. 05, 1989

The Examiner has rejected claims 1, 2, 4 to 7, 9 to 14, 16 to 27 and 35 to 54 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Conte, WO '066 and Banker.

DISCUSSION

We have carefully reviewed the claims, specification and applied prior art, including all of the arguments advanced by both the Examiner and Appellant in support of their respective positions. This review leads us to conclude that the Examiner's § 103 rejection is not well founded. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984).

Rather than reiterate the conflicting viewpoints advanced by the Examiner and Appellant concerning the above-noted rejection, we refer to the Answer and the Brief and Reply Brief.

Appellant's invention is directed to a composition for controlled delivery of an active substance in to aqueous medium by erosion, at a preprogramed rate, of the composition. (Brief, p. 2). Claim 1, which is representative of the claimed invention, appears below:

1. A composition for controlled delivery of at least one active substance into an aqueous medium by erosion of at least one surface of the composition, wherein said erosion occurs at a preprogrammed rate, comprising
 - i) a matrix comprising the active substance, wherein the matrix is erodible in the aqueous medium in which the composition is used and wherein the matrix allows substantially no diffusion of water into the composition beyond any exposed surface layers of the matrix, and
 - ii) a coating having at least one opening exposing at least one surface of said matrix, the coating comprising
 - a) a first cellulose derivative which has thermoplastic properties and which is substantially insoluble in the aqueous medium in which the composition is used,and at least one of
 - b) a second cellulose derivative which is soluble or dispersible in water,

c) a plasticizer, and

d) a filler,

wherein said coating crumbles and/or erodes upon exposure to the aqueous medium, at a rate which is equal to or slower than the rate at which the matrix erodes in the aqueous medium, allowing controlled exposure of said surface of the matrix to the aqueous medium.

Since we reverse the Examiner's rejection, we need to address only the independent claims, i.e., claims 1, 43, 52 and 54.

The claimed subject matter of claims 1, 43, 52 and 54 requires a matrix and a coating on the matrix. All of the claims require the coating to crumble and/or erode upon exposure to the aqueous medium, at a rate which is equal to or slower than the rate at which the matrix erodes in the aqueous medium.

The Examiner asserts the claimed invention is obvious over the combination of Conte, WO '066 and Banker. Specifically, the Examiner asserts that "[i]t would have been obvious to one of ordinary skill to use the matrix in [WO] '066 in the composition of Conte et al. for the beneficial effect of a constantly eroding [the] matrix surface and to include lauryl alcohol in [to] the 'support' layer for its beneficial effects as an additive in view of Banker." (Answer, p. 4).

In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have

led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. *See, e.g., Heidelberg Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) (When the patent invention is made by combining known components to achieve a new system, the prior art must provide a suggestion, or motivation to make such a combination.); *Northern Telecom v. Datapoint Corp.*, 908 F.2d 931, 934, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990) (It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor.); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1044, 1051, 5 USPQ 1434, 1438 (Fed. Cir. 1988).

We do not agree with the Examiner's obviousness determination. Conte describes a composition that contains an active substance in a matrix core. The matrix is characterized as swelling on contact with aqueous liquids. (Col. 2, ll. 41-44). The composition also contains a support for the matrix that partly covers the matrix core. (Col. 1, ll. 65-66). The support is also characterized by the property of remaining intact until the complete release of the active substance in the matrix

core. (Col. 2, ll. 5-8). Thus, the composition of Conte has at least two differences from the claimed invention. First, the matrix core of Conte swells when contacted with an aqueous liquid. Second, the support coating of Conte remains intact until complete release of the active substance from the core.

WO '066 describes a composition that contains an active substance in a matrix core. The matrix is characterized as eroding on contact with aqueous liquids.

We agree with Appellant, Brief pages 7-9, that there is no motivation to combine the teachings of Conte and WO '066 and if the combination were made as proposed by the Examiner the result would not have been the claimed invention. A person of ordinary skill in the art would have no motivation to replace the swellable matrix of Conte with an eroding matrix described by WO '066. Moreover, even if such a substitution were made, the result would have been a composite that had an eroding matrix and a support that would have remained intact until after the matrix has eroded to deliver the active substance.

The record indicates that the motivation relied upon by the Examiner suggesting the combination of Conte, WO '066 and Banker came from the Appellant's description of their invention in the specification rather than coming from the applied prior art and that, therefore, the Examiner used impermissible

hindsight in rejecting the claims. *See W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983); *In re Rothermel*, 276 F.2d 393, 396, 125 USPQ 328, 331 (CCPA 1960). For the reasons stated above and in Appellant's Briefs we reverse the Examiner's rejection under 35 U.S.C. § 103(a).

Since we reverse for the lack of the presentation of a *prima facie* case of obviousness by the Examiner, we need not reach the issue of the sufficiency of the evidence as allegedly demonstrating unexpected results. *See In re Geiger*, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987).

OTHER ISSUES

Prior to disposition of the present application, the Examiner should re-evaluate the patentability of the claimed subject matter over the WO '066 reference. WO '066 describes a composition that comprises an erodible matrix, containing an active substance, and a coating that can comprise a cellulose derivative. The Examiner should determine if the description of the coating composition in the claims requires more than one cellulose derivative and whether it would have been

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obvious to add an additional cellulose derivative to the coating composition of
WO '066.⁴

CONCLUSION

The rejection of claims 1, 2, 4 to 7, 9 to 14, 16 to 27 and 35 to 54 as
unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Conte,
WO '066 and Banker is reversed.

REVERSED

EDWARD C. KIMLIN
Administrative Patent Judge

JEFFREY T. SMITH
Administrative Patent Judge

LINDA R. POTEATE
Administrative Patent Judge

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⁴ We note that the claimed invention uses Markush language in describing the components of the coating. Thus, all of the components b, c and d are not required to be present in the coating composition.

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